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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,280	03/25/2004	James Gharib	071US1	6044
30328	7590	06/25/2007		
JONATHAN SPANGLER NU VASIVE, INC. 4545 TOWNE CENTRE COURT SAN DIEGO, CA 92121			EXAMINER FOREMAN, JONATHAN M	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 06/25/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/809,280	Applicant(s) GHARIB ET AL.	
	Examiner Jonathan ML Foreman	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/12/04; 5/9/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements filed 7/12/04 and 5/9/05 comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. They have been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits. However, NPL documents that provide no date, or only a partial date wherein the year of publication is not sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the particular month of publication is not in issue have been lined through (See MPEP 609.04(a)).

Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. See MPEP 609.05(b). Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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2. Claims 1 – 3 and 5 – 8 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S.

Patent Application No. 2002/0007129 to Marino.

In regard to claims 1 – 3 and 5 – 8, Marino discloses a system for performing surgical procedures and assessments, including a surgical accessory having at least one stimulation electrode (21, 22); and a processing system having at least one of computer programming software, firmware and hardware [0034] capable of stimulating said at least one stimulation electrode on a surgical accessory [0019], measuring the response of nerves depolarized by said stimulation [0020], determining a relationship between the surgical accessory and the nerve based upon the response measured, and communicating said relationship to a user, wherein said relationship may be used to determine at least one of nerve proximity, nerve direction, pedicle integrity, and neural pathology (See Abstract). The response of said depolarized nerves is measured by monitoring the EMG waveforms of myotomes associated with said depolarized nerves [0020]. The surgical accessory includes a system for establishing an operative corridor to a surgical site [0018]. The corridor may be established via a lateral, trans-psoas approach. It is noted that a recitation with respect to the manner in which an apparatus is intended to be employed does not impose any structural limitation upon the claimed apparatus that differentiates it from a prior art reference disclosing the structural limitations of the claim. *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1947); *In re Yanush*, 477 F.2d 958, 177 USPQ705 (CCPA 1973); *In re Finsterwalder*, 436 F.2d 1028, 168 USPQ 530 (CCPA 1971); *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 136 USPQ 458 (CCPA 1963); *Ex parte Masham*, 2 USPQ2d 1647 (BbPatApp & Inter 1987). The surgical accessory includes a pedicle testing device including a handle and pedicle probe capable of testing of the interior of a hole formed in a pedicle or a pedicle screw after insertion into the hole [0018].

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Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent

Application No. 2002/0007129 to Marino in view of U.S. Patent No. 6,926,728 to Zucherman et al.

In regard to claim 4, Marino discloses a system for establishing an operative corridor, and discloses that the stimulation electrode can be positioned near a distal end of any medical device, but fails to disclose the system for establishing an operative corridor to a surgical target side including a series of sequential dilator cannulae. Zucherman et al. teaches a system for establishing an operative corridor to a surgical target side including a series of sequential dilator cannulae (Claim 1). It would have been obvious in view of Zucherman et al to modify the system as disclosed by Marino to include a series of sequential dilator cannulae in order to allow the physician to establish a desired diameter of the corridor with a single device (Col. 1, lines 25 – 29).

5. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent

Application No. 2002/0007129 to Marino in view of U.S. Patent No. 6,292,701 to Prass et al.

In regard to claim 9, Marino discloses a pedicle testing device that includes a handle and the transmission of a stimulation signal to the probe, but fails to disclose a button on the handle for initiating the transmission of the stimulation signal from the processing system to the probe. Prass et al. teach a simulation probe having a handle and a button (105) on the handle for initiating the transmission of the stimulation signal from a processing system to the probe. It would have been

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obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Marino to include a button on the handle of the probe as taught by Prass et al. in order to allow the user to test the proximity of the probe at any desired time.

6. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application No. 2002/0007129 to Marino in view of U.S. Patent No. 6,425,859 to Foley et al.

In regard to claims 10 and 11, Marino discloses a system for monitoring nerve function through one of monopolar or bipolar stimulation and discloses that the stimulation electrode can be positioned near a distal end of any medical device, but fails to disclose the medical device including a nerve root retractor. Foley et al. teach a nerve root retractor for retracting a nerve (Figure 4). It would have been obvious to one having ordinary skill in the art to modify the medical device as disclosed by Marino to include a nerve root retractor as taught by Foley et al. to locate the spinal nerve root in order to gently move and hold the nerve root outside the working space (Col. 14, lines 15 – 17).

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application No. 2002/0007129 to Marino in view of U.S. Patent No. 6,425,859 to Foley et al. as applied to claim 10 above, and further in view of U.S. Patent Application No. 2001/0039949 to Loubser.

In regard to claim 12, Marino in view of Foley et al. disclose a nerve root retractor that includes a handle (72) and a blade (Figure 4), but fail to disclose the handle and blade being detachable. Loubser teaches a retractor having a detachable handle and blade (Figure 4A). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the nerve root retractor as disclosed by Marion in view of Foley et al. to include a detachable

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handle and blade as taught by Loubser in order to create a reusable handle and a disposable blade [0085].


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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